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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

JAMES O'BRIEN, *Plaintiff*, v. **EXACTECH, INC.,** **EXACTECH, US, INC.**, and **JOHN DOE DEFENDANTS 1-100,** *Defendants.*	Civil Action No.: 2:22-cv-5240 **COMPLAINT & DEMAND FOR JURY TRIAL**

Plaintiff, JAMES O'BRIEN, by and through his counsel, complains and alleges against Defendants, EXACTECH, INC., EXACTECH, US, INC., and JOHN DOE DEFENDANTS 1-100 allege as follows:

INTRODUCTION

1. Plaintiff brings this action for personal injuries and damages suffered as a direct and proximate result of the use of an unreasonably dangerous device, the Exactech Connexion GXL liner (hereinafter "the Product").

2. The Product was used in the plaintiff JAMES O'BRIEN's bilateral total hip arthroplasty to treat his severe osteoarthropathy of the bilateral hip joints.

3. At all times relevant to this action, Defendants were responsible for the design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product to be used by healthcare providers in patients throughout the United States, including New York.

4. All of plaintiff JAMES O'BRIEN's claims for damages relate to Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product.

5. The Product reached plaintiff JAMES O'BRIEN, by and through his physicians, and medical facilities without substantial change in condition from the time it left Defendants' possession.

6. Plaintiff JAMES O'BRIEN, his physicians, and his medical providers used the Product in the manner in which it was intended.

PARTIES

7. Plaintiff, JAMES O'BRIEN, currently resides in Lincoln Park, New Jersey.

8. EXACTECH, INC. is a Delaware corporation with a principal place of business at 2320 NW 66th CT Gainesville, Florida 32653. Exactech's stated business purpose is to develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and

internationally and to introduce its products, including the Product, into interstate commerce, either directly or indirectly through third parties or related entities.

9. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

10. According to public filings, Defendant EXACTECH US, INC., conducts Defendants' U.S. sales and distribution activities.

11. EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including the products at issue here, into commerce throughout the United States.

12. Upon information and belief, Defendant EXACTECH, INC.'s products were distributed by Defendant EXACTECH US, INC., throughout the United States, including in New York, New York where Plaintiff received his implant.

13. At all times relevant to this action, Defendant EXACTECH US, INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold EXACTECH, INC.'s products in interstate commerce and generated substantial revenue as a result.

14. Plaintiff JAMES O'BRIEN is unaware of the true names and capacities of the Defendants sued herein as JOHN DOE DEFENDANTS 1-100 and therefore sues said Defendants by such fictitious names. Plaintiff JAMES O'BRIEN is informed and believes and therefore alleges such fictitiously named Defendants are or may be responsible in some manner for the occurrences herein alleged, and that plaintiff JAMES O'BRIEN's damages, as herein alleged, were

proximately caused by their conduct. Plaintiff JAMES O'BRIEN is informed and believes and therefore alleges that at all times herein mentioned, Defendants, and each of them, were the agents, servants and/or employees of each of the other Defendants herein and were acting with the permission and consent and within the course and scope of said agency and employment.

JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and all Defendants.

16. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of New Jersey. At all relevant times Defendants transacted, solicited, and conducted business in New Jersey through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in New Jersey.

17. Venue is proper in this judicial district and division pursuant to 28 U.S.C. § 1391 because Plaintiff is a resident and citizen of Morris County, New Jersey.

FACTS

18. Plaintiff JAMES O'BRIEN underwent a bilateral total hip arthroplasty to his hips in approximately 2017. The surgery was performed in New York, New York, using Defendants' Novation Crown. Specifically, as mentioned above, the issue in this matter is with the premature wear of the polyethylene, cross linked Exactech Connexion GXL liners (hereinafter "the Product"), which led to the plaintiff JAMES O'BRIEN's premature, debilitating osteolysis.

19. The Product was used for its intended purpose because plaintiff JAMES O'BRIEN suffered from osteoarthropathy of both hips.

20. After Plaintiff JAMES O'BRIEN received a total bilateral hip arthroplasty, with the Product, Plaintiff JAMES O'BRIEN suffered premature osteolysis and experienced severe pain and discomfort in both his hips.

21. Due to the failure of the Product, Plaintiff JAMES O'BRIEN suffered injuries so painful that a total bilateral hip arthroplasty revision was recommended by his medical professionals.

22. Due to premature wear and/or loosening of the Product, Plaintiff is scheduled for bilateral revision surgery to be performed in approximately August 2022, in New York, New York.

23. Plaintiff JAMES O'BRIEN continues to experience severe pain and discomfort in both his hips.

24. Defendants designed, manufactured, distributed, and placed into the stream of commerce the Product and its components, during the relevant time period.

25. Defendants performed, completed, and were solely responsible for the design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product.

26. Defendants had in their possession, during the relevant time period, testing, research and studies regarding loosening and failure of the Product.

27. Defendants had in their possession, during the relevant time period, information regarding the rate of loosening and failure of the Product.

28. The Product was first marketed by Exactech in 2007.

29. The product was indicated for use for adults, inter alia, undergoing a total hip arthroplasty due to osteoarthritis, rheumatoid arthritis, etc.

30. Defendants applied for U.S. Food and Drug Administration ("FDA") clearance to

market the Product under Section 510(k) of the Medical Device Amendment.

31. Section 510(k) allows for the marketing of medical devices, so long as the medical device or material is deemed substantially equivalent to other legally marketed predicate devices or materials without predicate devices. There is no formal review for the safety or efficacy of the device. It is imperative to note that a 510(k) approval is not the same as FDA approval.

32. Defendants obtained clearance by a 510(k) application on March 15, 2007.

33. Based on the 510(k)-clearance procedure, Defendants bypassed the requirement to have the Product independently evaluated by the FDA or its experts.

34. Defendants used irradiated ultra-high-molecular-weight polyethylene ("UHMWPE") plastic in the Product.

35. UHMWPE has been used clinically in joint implants due to its low friction, high wear resistance, good toughness, high impact strength, high resistance to corrosive chemicals, excellent biocompatibility, and low cost.

36. However, there is an unacceptably low stability of oxidation of polyethylene. Consequently, two stabilization strategies were developed and adopted in order to minimize post-irradiation oxidative ageing: one involved post-irradiation melting of the polyethylene ("remelting"), while the other included a thermal treatment, but at a temperature below complete melting of the crystallites ("annealing"). The rationale for the protocol was to eliminate or reduce an increased rate of oxidation of the polymer.

37. The Product was neither remelted nor annealed, leading to the premature wear of the Product, the onset of Plaintiff JAMES O'BRIEN's osteolysis and the need for the Plaintiff JAMES O'BRIEN's revision surgery.

38. The Product was removed from the market in 2019 and has since been recalled as

of June 29, 2021, due to 89,050 devices being impacted by premature wear.

39. The Product was subject to a further recall as of August 2022, when Exactech expanded its 2021 recall communication to include all nonconforming conventional UHMWPE liners manufacture since 2004, which enabled increased oxygen diffusion in the polyethylene insert resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen layer. Over time, oxidation can severely degrade the mechanical properties of the Product polyethylene, leading to both the accelerated wear and bone loss, and/or component fatigue cracking/fracture, all leading to revision surgery.

40. Prior to the Product being implanted in Plaintiff, Exactech had been informed (based on product complaint date) that the Product was susceptible to premature, excessive wear in patients and that revision surgeries would be necessary to remove the Product.

41. Defendants now offer a new liner that replaced the Product. The "XLE Liner," which was released in 2019, has a lower wear rate than the Product, and is annealed and blended with vitamin E. The "XLE" Liner is manufactured differently and subjected to a different, more thorough treatment than the Product.

TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

42. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including the discovery rule and/or fraudulent concealment.

43. Plaintiff files this lawsuit within the applicable statute of limitations period of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering the cause of his injuries and the wrongful conduct that caused such injuries. Plaintiff could not by exercise of reasonable diligence have discovered any wrongdoing,

nor could have discovered the causes of Plaintiff's injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiff's injuries were discovered, their causes were not immediately known. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence should have discovered, that Plaintiff may have a basis for an actionable claim.

44. The discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff discovered or reasonably should have discovered Plaintiff's injury and the causal connection between the injury and Defendants' conduct.

45. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the truth, quality and nature of Plaintiff's injuries and the connection between the injuries and Defendants' tortious conduct. Defendants, through their affirmative misrepresentations, concealment, and omissions, actively concealed from Plaintiff the risk their abusers continued to pose.

46. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with their Product and because Defendants knew that this information was not available to Plaintiff. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

47. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

48. Under the appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

COUNT I
NEGLIGENCE
(Against all Defendants)

49. Plaintiff JAMES O'BRIEN repeats, reiterates, incorporates and realleges each and every paragraph and allegation contained in this Complaint with the same force and effect as if fully set forth herein.

50. Defendants had a duty to plaintiff JAMES O'BRIEN to exercise reasonable care in the design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product, including the duty to take all reasonable steps necessary to manufacture and sell a Product that was not defective and unreasonably dangerous to consumers and users of the Product.

51. Defendants failed to exercise reasonable care in the design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of the Product because Defendants knew, or should have known, that its Product would prematurely loosen and fail.

52. Defendants knew, or should have known, that consumers, such as the plaintiff JAMES O'BRIEN, and/or his healthcare providers would foreseeably suffer injuries (osteolysis), as a result of Defendants' failure to exercise ordinary care, for the following reasons:

a. The design of the Product posed a greater likelihood for failure and was more dangerous than other available devices indicated for the same conditions and uses;

b. The Product was never approved by the FDA as being safe and effective for its intended uses; and

c. Through the 510(k) certification Defendants wrongfully told the FDA that the Product was "substantially equivalent" to other hip replacement products on the

market, and the Defendants were wrongfully able to avoid safety review protocols required for premarket approval under FDA regulations.

53. As a foreseeable, direct, and proximate consequence of Defendants' negligence, plaintiff JAMES O'BRIEN sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs, and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT II
STRICT PRODUCTS LIABILITY: DESIGN DEFECT
(Against all Defendants)

54. Plaintiff JAMES O'BRIEN repeats, reiterates, incorporates and realleges each and every paragraph and allegation contained in this Complaint with the same force and effect as if fully set forth herein.

55. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Product that was surgically implanted in plaintiff JAMES O'BRIEN.

56. The Product was expected to, and did, reach the intended consumers (including plaintiff), handlers, and persons encountering the Product with no substantial change in the condition in which the Product was designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed by Defendants.

57. The Product was marketed by Defendants for use in hip replacement surgeries for consumers, and plaintiff JAMES O'BRIEN became a consumer in approximately 2017 (his original surgery date) and relied upon the safety of the Product.

58. Even though UHMWPE is commonly used when performing hip revision surgery, the Product was inadequately and inappropriately designed through the lack of remelting and/or annealing.

59. The Product was inadequately and inappropriately tested due to Defendants never seeking or receiving FDA approval.

60. The Product was designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed and sold in a defective condition, for use by plaintiff JAMES O'BRIEN and plaintiff JAMES O'BRIEN's physicians and/or healthcare providers, and all other consumers of the Product, making the Product unreasonably dangerous. In particular, the Product was defectively designed in that the liner was neither remelted nor annealed, which led to the premature wear of the Product, the plaintiff JAMES O'BRIEN's contraction of osteolysis, and the need for the plaintiff JAMES O'BRIEN's revision surgery. The Product caused serious and permanent injuries to the Plaintiff.

61. While UHMWPE is commonly used when performing a hip revision surgery, Defendants' Product, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and formulation, because when it left the hands of Defendants, the Product was neither remelted nor annealed, was unreasonably dangerous and more dangerous than expected by the ordinary consumer.

62. At all times relevant to this action, Defendants knew and had reason to know that the Product was inherently defective and unreasonably dangerous as designed, formulated, and

manufactured by Defendants, and when used in the form manufactured and distributed by Defendants, and in the manner instructed by Defendants to be used and implanted in the plaintiff JAMES O'BRIEN and other consumers.

63. Through Defendants' lack of obtaining FDA approval, Defendants knew, or were reckless in not knowing, that said products were in a defective condition and that those who were implanted with such devices were at an unreasonably high risk of suffering injury.

64. Defendants knew and intended that the Product would be purchased from Defendants by hospitals and physicians, and would be used by such purchasers without any detailed inspection for defects, and which purchasers would rely upon the representations made by Defendants on the product label, in other promotional sales and materials otherwise.

65. Plaintiff JAMES O'BRIEN and plaintiff JAMES O'BRIEN's physicians and/or healthcare providers used the Product for the purpose intended by Defendants, and in a manner normally intended to be used.

66. Plaintiff JAMES O'BRIEN and plaintiff JAMES O'BRIEN's physicians could not have discovered any defect in the Product or accompanying sales and promotional materials through the exercise of due care.

67. At all times material to these claims, there was a safer, alternative design that was both technologically and economically feasible, which would have prevented or substantially reduced the risk of plaintiff JAMES O'BRIEN's injuries without substantially impairing the device's utility.

68. As a direct and proximate consequence of Defendants' design defects, plaintiff JAMES O'BRIEN sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a

diminished quality of life, medical and related expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT III
STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT
(Against all Defendants)

69. Plaintiff JAMES O'BRIEN repeats, reiterates, incorporates and realleges each and every paragraph and allegation contained in this Complaint with the same force and effect as if fully set forth herein.

70. The Product implanted in plaintiff JAMES O'BRIEN had an impurity, imperfection, and/or another product defect permitted to be created, contained, or placed within the product in the manufacturing process such that it would experience premature, excessive polyethylene wear, rendering it unreasonably dangerous.

71. The impurity, imperfection, and/or other product defect was a deviation from design and quality manufacturing standards.

72. As a result of the impurity, imperfection, and/or other product defect, the Product implanted in plaintiff JAMES O'BRIEN was in a defective condition, such that it would experience excessive polyethylene wear, and it was unreasonably dangerous when it left the Defendants' control.

73. Defendants knew or should have known that the Product implanted in plaintiff JAMES O'BRIEN would not be inspected for impurities, imperfections and/or other product

defects prior to its implantation into plaintiff JAMES O'BRIEN, and that if it were inspected for such impurities, imperfections and/or other product defects by plaintiff JAMES O'BRIEN or his healthcare providers, the same could not be discerned or perceived.

74. The product implanted in plaintiff JAMES O'BRIEN was used in the manner intended.

75. As a direct and proximate consequence of Defendants' manufacturing defects, plaintiff JAMES O'BRIEN sustained serious personal injuries and related losses including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IV
STRICT PRODUCTS LIABILITY: FAILURE TO WARN
(Against all Defendants)

76. Plaintiff JAMES O'BRIEN repeats, reiterates, incorporates and realleges each and every paragraph and allegation contained in this Complaint with the same force and effect as if fully set forth herein.

77. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Product.

78. Defendants were expected to, and did, reach the intended consumers, handlers, and persons encountering the Product with no substantial change in the condition in which the Product

was designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed by Defendants.

79. Use of the Product, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendants, involved a substantial danger to plaintiff JAMES O'BRIEN that would not be readily recognized by the ordinary user of the Product.

80. Plaintiff JAMES O'BRIEN used the Product as intended or in a reasonably foreseeable manner.

81. Defendants failed to provide adequate warnings to avoid the substantial danger of premature wear.

82. Specifically, since the 1990's (the Product was approved for sale in 2005) manufacturers of hip implants developed the methods of remelting or annealing to avoid the premature wear of their hip implants. The Product was neither remelted nor annealed and Defendants failed to warn of the possibility of premature wear due to the Product's lack of standard, industrial conformity.

83. Additionally, the Defendants received 510(k) approval due to their contention that the Product was substantially equivalent to other legally marketed devices, even though the Product was neither remelted nor annealed as was standard in the industry.

84. The Product never received FDA approval and has since been recalled as of July 22, 2021. It has been indicated that 89,050 devices were impacted by premature wear.

85. As a proximate result of Defendants' acts and omissions and the plaintiff JAMES O'BRIEN's use of Defendants' defective Product, plaintiff JAMES O'BRIEN suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint,

including, but not limited to, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical bills and other expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT V
BREACH OF EXPRESS WARRANTY
(All Defendants)

86. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

87. Defendants, through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that their Product was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, severe pain and surgery, and was adequately tested and fit for its intended use.

88. At the time of making such express warranties, Defendants knew and/or should have known that their Product did not conform to the express warranties and representations. In fact, their Product exacerbated the risk of severe pain and revision surgery, and Defendants had full knowledge of this and did not accurately or adequately warn the plaintiff JAMES O'BRIEN, his physicians and/or other healthcare providers.

89. The Product manufactured and sold by Defendants did not conform to these

representations because it caused serious injury, including severe pain and surgery, to consumers such as the plaintiff JAMES O'BRIEN.

90. Defendants breached their express warranties because the Product was and is defective for its intended purpose.

91. Plaintiff JAMES O'BRIEN, through his physicians and/or other healthcare providers, did rely on Defendants' express warranties regarding the safety and efficacy of their Product in purchasing and using the Product.

92. Members of the medical community, including physicians and other healthcare professionals, relied upon Defendants' representations and express warranties in connection with the use recommendation, description, and use of Defendants' Product.

93. As a foreseeable, direct, and proximate result of the breach of the express warranties, the plaintiff JAMES O'BRIEN suffered severe and permanent personal injuries, harm, and economic loss.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against Defendants and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VI
BREACH OF IMPLIED WARRANTY
(All Defendants)

94. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

95. At all times relevant to this action, Defendants manufactured, compounded,

portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold their Product for hip replacement.

96. Defendants knew of the intended use of their Product at the time Defendants marketed, sold, and distributed the Product for use by the plaintiff JAMES O'BRIEN's physicians and healthcare providers, and impliedly warranted the Product to be of merchantable quality and safe and fit for its intended use.

97. Defendants impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including plaintiff JAMES O'BRIEN, his physicians, and h i s healthcare providers, that Product was safe and of merchantable quality and fit for the ordinary purpose for which the Product was intended and marketed to be used.

98. Defendants' representations and implied warranties were false, misleading, and inaccurate because the Product was defective, and not of merchantable quality.

99. At the time Defendants' Product was promoted, marketed, distributed, and/or sold by Defendants, Defendants knew of the use for which it was intended and impliedly warranted the Product to be of merchantable quality and safe and fit for such use.

100. Plaintiff JAMES O'BRIEN, his physicians and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of Defendants, as manufacturer, developer, distributor, and seller of the Product, as to whether it was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Product was manufactured and sold.

101. Contrary to Defendants' implied warranties, its Product as used by plaintiff JAMES O'BRIEN, was not of merchantable quality and was not safe or fit for its intended use because the

Product was unreasonably dangerous as described herein.

102. Defendants breached their implied warranty because the Product was not safely fit for its intended use and purpose.

103. Defendants placed the Product into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the Product was expected to and did reach the plaintiff JAMES O'BRIEN without substantial change in the condition in which it was manufactured and sold.

104. As a foreseeable, direct and proximate result of Defendants' acts and omissions and plaintiff JAMES O'BRIEN's use of Defendants' defective Product, plaintiff JAMES O'BRIEN suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for his injuries described herein.

WHEREFORE, Plaintiff JAMES O'BRIEN demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VII
FRAUDULENT MISREPRESENTATION
(All Defendants)

105. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

106. Defendants were under a duty to accurately and truthfully disclose to the plaintiff JAMES O'BRIEN, his physicians, and healthcare providers, that the product had not been adequately tested and had not been found to be safe and effective for the treatment of patients, like

plaintiff JAMES O'BRIEN in this matter, requiring hip replacement.

107. Defendants, by and through agents and employees as will be added following discovery, intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and consumers, including the plaintiff JAMES O'BRIEN and his health care providers, that the Product had been adequately tested in clinical trials and was found to be safe and effective.

108. Defendants knew or should have known at the time it made its fraudulent misrepresentations, that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of its Product. Defendants made their fraudulent misrepresentations intentionally, willfully, wantonly, and/or with reckless disregarded and depraved indifference for the safety and well-being of the users of their Product, including the plaintiff JAMES O'BRIEN.

109. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, the plaintiff JAMES O'BRIEN, and the public, and also inducing the medical community, plaintiff JAMES O'BRIEN, and the public, to recommend, prescribe, insert and purchase Defendants' Product.

110. Defendants had sole access to material facts concerning the defective nature of the Product and its propensity to cause serious and dangerous injuries and damages to persons who used the Product.

111. The intentional concealment and omissions of material fact concerning the safety of the Product was undertaken purposefully, willfully, wantonly, fraudulently with intent to mislead, and/or with reckless disregard for the health and safety of the plaintiff JAMES O'BRIEN and to induce plaintiff JAMES O'BRIEN's physicians and healthcare providers to purchase, prescribe, and/or implant the Product.

112. Defendants purposefully, willfully, wantonly, fraudulently with intent to mislead, and/or with reckless disregard misled plaintiff JAMES O'BRIEN into reliance upon Defendants' fraudulent misrepresentations that the Product was safe and effective for use.

113. At the time Defendants made these misrepresentations, during the relevant time period, including Defendants through its various officers, directors, agents, representatives, and employees, and at the times the plaintiff was implanted with Defendants' Product, plaintiff JAMES O'BRIEN and his healthcare advisers were unaware of Defendants' falsehoods, and reasonably relied on the Defendants' misrepresentations.

114. Defendants knew and had reason to know that the Product was at great risk of causing serious personal injury to users of the Product, and that the Product was inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given by Defendants.

115. In reliance upon Defendants' false and fraudulent misrepresentations, through his physicians and healthcare providers, the plaintiff JAMES O'BRIEN was induced to, and did, reasonably rely upon Defendants' misrepresentations regarding the safety and efficacy of the Product in 2013, thereby sustaining severe and permanent personal injuries and damages. Defendants knew and had reason to know that, plaintiff JAMES O'BRIEN, his physicians and his healthcare providers, in using the Product, did not have the ability to determine the true facts intentionally concealed by Defendants, and would not have used the Product if the true facts regarding the Product had been known by plaintiff JAMES O'BRIEN, his physicians, and his healthcare providers.

116. As a result of Defendants' research and testing, or lack thereof, Defendants willfully, wrongfully, and intentionally distributed false information including, but not limited to, assuring the plaintiff JAMES O'BRIEN, the public, and plaintiff JAMES O'BRIEN's healthcare

providers and physicians, that the Product was safe for use. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed from the medical community, plaintiff JAMES O'BRIEN and other consumers the true results of Defendants' studies and research, which revealed the true risks of serious harm associated with the use of the Product.

117. Defendants had a duty when disseminating information to the public to provide truthful information, and a parallel duty not to deceive the public, the plaintiff JAMES O'BRIEN, his healthcare providers and physicians, and the FDA.

118. The information distributed by Defendants to the public, including the plaintiff JAMES O'BRIEN, the medical community, and the FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of the Product.

119. Defendants intentionally, falsely represented the risks in using the Product to the public at large, and the plaintiff JAMES O'BRIEN and his healthcare providers in particular, for the purpose of influencing the sales of a product known by Defendants to be dangerous and defective.

120. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and purposefully.

121. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, plaintiff JAMES O'BRIEN was caused to suffer the injuries described in this Complaint.

122. As a direct and proximate consequence of Defendants' fraudulent

misrepresentations, plaintiff JAMES O'BRIEN sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VIII
FRAUDULENT CONCEALMENT
(All Defendants)

123. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

124. At all times during the course of dealing between Defendants and plaintiff JAMES O'BRIEN, and/or, plaintiff JAMES O'BRIEN's healthcare providers, and/or the FDA, Defendants misrepresented material facts about the safety of the Product for its intended use.

125. Defendants failed to mention the likelihood of needing subsequent surgery, or the likelihood of premature wear and loosening causing the need for extensive debridement of the entire joint space.

126. Defendants were under a duty to disclose to plaintiff JAMES O'BRIEN, and plaintiff JAMES O'BRIEN's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Product.

127. Defendants had sole access to material facts concerning the defective nature of the

product and its propensity to cause serious and dangerous side effects, including surgery, and hence, cause damage to persons who used the Product. Through the 510(k) certification Defendants wrongfully told the FDA that the Product was "substantially equivalent" to other hip replacement products on the market, and the Defendants were wrongfully able to avoid safety review protocols required for premarket approval under FDA regulations.

128. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the Product was made purposefully, willfully, wantonly, and/or recklessly, to mislead and induce plaintiff JAMES O'BRIEN, and plaintiff JAMES O'BRIEN's physicians, hospitals and healthcare providers into reliance, continued use of the Product, and actions thereon, and to cause them to purchase, prescribe and/or dispense the device and/or use the product. Defendants' misrepresentations were made with knowledge that their statements were false.

129. Defendants knew that plaintiff JAMES O'BRIEN, and plaintiff JAMES O'BRIEN's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Product, as set forth herein.

130. Plaintiff JAMES O'BRIEN and plaintiff JAMES O'BRIEN's physicians, prior to the date of plaintiff JAMES O'BRIEN's total hip replacement surgery, relied on the Defendants' misrepresentations about the Product to use the Product in treating plaintiff JAMES O'BRIEN.

131. Defendants' misrepresentations induced the use of their product to plaintiff JAMES O'BRIEN and plaintiff JAMES O'BRIEN's physicians.

132. Plaintiff JAMES O'BRIEN, as well as plaintiff JAMES O'BRIEN's doctors, healthcare providers, and/or hospitals reasonably relied on facts which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

133. As a result of the foregoing acts and omissions and as a direct and proximate consequence of Defendants' fraudulent misrepresentations, plaintiff JAMES O'BRIEN was caused to suffer and/or was at a greatly increased risk of serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

134. WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against the Defendants and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IX
NEGLIGENT MISREPRESENTATION
(All Defendants)

135. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

136. Defendants had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including plaintiff JAMES O'BRIEN, the truth regarding Defendants' claims that the Product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Defendants, in fact, were false and Defendants were careless or negligent in ascertaining the truth of the representations at the time Defendants made the misrepresentations.

137. Defendants represented and marketed the Product as being safe and effective.

138. After Defendants became aware of the risks of the Product, Defendants failed to

communicate to the plaintiff JAMES O'BRIEN and other members of the general public, that the Product had an increased risk of severe pain and surgery along with a likelihood for premature wear.

139. Defendants failed to exercise ordinary care in making representations concerning its Product and its manufacture, sale, testing, quality assurance, quality control, and distribution in the stream of commerce. Defendants negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the Product's unreasonable, dangerous and adverse side effects associated with the implantation, use of the Product.

140. Defendants breached its duty in representing to the plaintiff JAMES O'BRIEN, his physicians and healthcare providers, and the medical community that the Product did not carry the risk of injuries such as those suffered by plaintiff JAMES O'BRIEN and other similarly situated patients.

141. Defendants failed to warn plaintiff JAMES O'BRIEN and other consumers, of the defective condition of the Product, as manufactured and/or supplied by Defendants.

142. Defendants negligently misrepresented material facts about the Product, inter alia its safety and testing, in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

143. The above misrepresentations were made to plaintiff JAMES O'BRIEN, as well as the general public.

144. Plaintiff JAMES O'BRIEN and his healthcare providers and physicians justifiably relied on Defendants' misrepresentations.

145. Consequently, plaintiff JAMES O'BRIEN's use of the Product was to his detriment as Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

146. As a foreseeable, direct, and proximate result of Defendants' negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Defendants knew, or had reason to know, that the Product had not been sufficiently tested, that the Product lacked adequate, accurate, and prominent warnings, and the implantation with the Product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

147. As a direct and proximate consequence of Defendants' negligent misrepresentations, the plaintiff JAMES O'BRIEN sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT X
UNJUST ENRICHMENT

148. Plaintiff JAMES O'BRIEN repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

149. Defendants are and at all times were the manufacturer, seller, and/or supplier of the

Product.

150. Plaintiff JAMES O'BRIEN paid for the Product for the purpose of hip replacement.

151. Defendants have accepted payment by plaintiff JAMES O'BRIEN for the purchase of their Product.

152. Plaintiff JAMES O'BRIEN has not received the safe and effective Product for which he paid.

153. It would be inequitable for Defendants to keep this money if plaintiff JAMES O'BRIEN, did not in fact receive safe and effective treatment for the hip replacement.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgment against Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT XI
PUNITIVE DAMAGES
(All Defendants)

154. Despite their knowledge, Defendants failed to, among other purposeful acts, inform or warn plaintiff JAMES O'BRIEN or plaintiff JAMES O'BRIEN's healthcare providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall the Product from the market.

155. At all times hereto, Defendants attempted to and did misrepresent facts concerning the safety of the Product.

156. At all times hereto, Defendants attempted to and did knowingly misrepresent the safety of the product.

157. At all times hereto, Defendants attempted to and did recklessly disregard the fact that the Product would fail and cause debilitating injuries necessitating a revision surgery and also recklessly failed to advise the plaintiff JAMES O'BRIEN, his physicians, and the FDA of the same.

158. Defendants knew of the Product's defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the product to maximize sales and profits at the expense of the health and safety of the public, including the plaintiff JAMES O'BRIEN, in conscious and/or negligent disregard of the foreseeable harm caused by the device.

159. As a foreseeable, direct, proximate, and legal result of Defendants' acts and omissions a described herein, plaintiff JAMES O'BRIEN has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses.

CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, plaintiff requests trial by jury and that the Court grant him the following relief against Defendants on all counts of the Complaint, including:

(A) Money damages representing fair, just and reasonable compensation for Plaintiff's common law and statutory claims;

(B) Lost wages;

(C) Punitive and/or treble damages pursuant to state law;

(D) Disgorgement of profits and restitution of all costs;

(E) Attorneys' fees pursuant to state law;

(F) Pre-judgement and post-judgement interests as authorized by law on the judgments which enter on Plaintiff's behalf;

(G) Cost of suit;

(H) Delay Damages; and

(I) Such other relief as is deemed just and proper.

WHEREFORE, plaintiff JAMES O'BRIEN demands judgement against Defendants for compensatory damages, punitive damages and costs of suit as provided by law.

Dated: August 25, 2022

ROBINS KAPLAN LLP

By: */s/Rayna E. Kessler*

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**Pro Hac Vice* motion to be filed

Attorneys for Plaintiff James O'Brien

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury.

Dated: August 25, 2022

Respectfully submitted:

By: */s/Rayna E. Kessler*

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**Pro Hac Vice* motion to be filed

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